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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,932	02/08/2002	Robert J. Nordstrom	MDS-022C1	1037

EXAMINER
QADERI, RUNA S

ART UNIT	PAPER NUMBER
3737	

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DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,932

Applicant(s)

NORDSTROM ET AL.

Examiner

Runa S Qaderi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/8/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3, 4, and 5.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,385,484. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are an obvious broadening of the patent claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 24-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeng et al. (6,069,689) in view of Richards-Kortum et al. (6,258,576).

With respect to claims 24-48 Zeng et al. reference discloses the method and the apparatus to perform the method of optical diagnosis of skin disorder or disease. The Zeng et al. reference relies on obtaining the fluorescence, reflectance, and Raman spectroscopy in characterizing the condition of the tissue. Such conditions include but are not limited to actinic keratosis, basal cell carcinoma, seborrheic keratosis, compound nevus, and squamous cell carcinoma, column 2 lines 8-17.

With respect to claims 24, 32, 38, 42, and 48 Zeng et al. teaches a light source for generating light to illuminate the tissue, a probe means optically connected to the light source for obtaining the fluorescence, reflectance and Raman scattering (additional optical information) from the tissue, spectral analysis means for optically connected to the probe means for generating and displaying spectral measurements of the fluorescence, reflectance, and Raman scattering to assist in diagnosing the tissue with respect to a plurality of comparison/reference spectra, column 2 lines 23-32. The reference notes that it is important to rely on at least two of fluorescence, reflectance, and Raman scattering when diagnosing the tissue because a single spectra makes it difficult to distinguish the condition of the tissue, column 11 line 58 through 12 lines 24.

With respect to claims 28 and 29 Zeng et al. teaches a ratio technique to aid spectra interpretation. In this technique, the tissue spectra are divided by the corresponding plurality normal/reference spectra. Although the Zeng et al. reference

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does not explicitly recite an average of the plurality reference spectra; the basic mathematically averaging process is obvious to one of ordinary skill in the art because it is a well known analysis technique. Furthermore applicant's limitation to residual amplitude is interpreted as providing for a remainder between the obtained spectra and the reference spectra that is satisfied by Zeng et al's ratio technique.

With respect to claims 24-48 Zeng et al. reference does not teach the system and method of optically diagnosing a tissue specimen(s) (in vitro diagnosis), said tissue specimen comprising human cervical tissue, said cervical diagnosis comprising one of the conditions of normal squamous tissue, metaplasia, CIN I, and CIN II/III, and said additional optical information comprising a video and/or optical image.

Richards-Kortum et al. teaches an optical diagnosis method and apparatus for cervical squamous intraepithelial lesions in vitro and in vivo using fluorescence and Raman spectroscopy. With respect to applicant claims it is obvious to one of ordinary skill in the art at the time the invention was made to provide for the system and method of Zeng et al. for tissue specimen diagnosis because it is well known to provide the same optical method and apparatus for both in vivo and in vitro examination as shown in Richards-Kortum et al.

Richards-Kortum et al. column 3 lines 45-46 discloses a plurality of tissue samples as taught in applicant claims 25, 35, 39, and 45. The limitation to a plurality of tissue specimen/samples is obvious to one of ordinary skill in the art because it allows the examiner to validate their diagnosis with multiple diagnosis attempts. In addition it has been held that mere duplication of the essential working parts of a device or

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working steps of a method involve only routine skill in the art. *St. Regis Paper Co. v.*

Bemis Co., 193 USPQ 8.

With respect to claims 26, 36, 40, and 46, it is obvious to one of ordinary skill in the art to provide for the system and method of Zeng et al. to diagnose human cervical tissue because optical analysis has the potential to improve the accuracy and efficacy of cervical pre-cancer screening and diagnosis as taught in Richards-Kortum et al., column 2 lines 13-26. On the same note, with reference to claims 27, 37, 41, and 47, the characterization of cervical tissue condition as one of normal squamous tissue, metaplasia, CIN I, and CIN II/III is obvious to one of ordinary skill at the time the invention was made because it is a well known characterization scheme of cervical precancer.

Finally with respect to claims 33, 34, 43, and 44 Richards-Kortum et al. teaches that tissue classification may be displayed as image of the cervix with the different tissue types displayed as different colors. This color display satisfies both limitations to video information and an optical image. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate the image display of Richards-Kortum et al. as the additional optical information in the invention of Zeng et al. because it is a more easily understandable displaying means as taught by Richards-Kortum. In addition it improves upon the diagnosis of the tissue by providing multiple analysis means as taught by Zeng et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 605-4285. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSQ

RSQ

Angela D. Sykes

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